PATENT COOPERATION TREA'.

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| Applicant's or agent's file reference BSCI00801WO | FOR FURTHER ACTION | See item 4 below | | | | |
|---|--|--|--|--|--|--|
| International application No. PCT/US2005/010146 | International filing date (day/month/year) 29 March 2005 (29.03.2005) | Priority date (day/month/year) 30 March 2004 (30.03.2004) | | | | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | | | | |
| Applicant BOSTON SCIENTIFIC LIMITED (INCORPORATED IN IRELAND) | | | | | | |

| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a). | | | | | | | | |
|--------|--|---|---|--|--|--|--|--|--|
| 2. | This REPORT consists of a total of 7 sheets, including this cover sheet. | | | | | | | | |
| | In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. | | | | | | | | |
| 3. | 3. This report contains indications relating to the following items: | | | | | | | | |
| | Box No. I | Basis of the report | | | | | | | |
| | Box No. II | Priority | | | | | | | |
| | Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | |
| | Box No. IV Lack of unity of invention | | | | | | | | |
| | Box No. V | Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | |
| | Box No. VI | Certain documents | cited | | | | | | |
| | Box No. VII | Certain defects in the | e international application | | | | | | |
| | Box No. VIII | Certain observation | s on the international application | | | | | | |
| 4. | 4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2). | | | | | | | | |
| | | | Date of issuance of this report 04 October 2006 (04.10.2006) | | | | | | |
| | The International Bur 34, chemin des Co 1211 Geneva 20, S | lombettes | Authorized officer Yoshiko Kuwahara | | | | | | |
| Facsi | mile No. +41 22 338 82 70 | | e-mail: pt07@wipo.int | | | | | | |
| Form 1 | PCT/IB/373 (January 2004) | | | | | | | | |

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| From the | • | |
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| INTERNATIONAL | SEARCHING | AUTHORITY |

see form PCT/ISA/220

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|-------|---|---|-----|------|
| WIPO | | | | PCT |

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

| | | Date of mailing (day/month/year) | see form PCT/ISA/210 (second sheet) |
|---|--|----------------------------------|---|
| Applicant's or agent's file reference see form PCT/ISA/220 | | FOR FURTHE See paragraph 2 b | |
| International application No. International filing date (c PCT/US2005/010146 29.03.2005 | | ay/month/year) | Priority date (day/month/year) 30.03.2004 |

International Patent Classification (IPC) or both national classification and IPC A61K35/28, A61P9/10

Applicant

BOSTON SCIENTIFIC SCIMED, INC.

| 1. | This opinion | contains | indications | relating | to the | following | items |
|----|--------------|----------|-------------|----------|--------|-----------|-------|
|----|--------------|----------|-------------|----------|--------|-----------|-------|

| \boxtimes | Box No. I | Basis of the opinion |
|-------------|--------------|--|
| | Box No. II | Priority |
| \boxtimes | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| | Box No. IV | Lack of unity of invention |
| \boxtimes | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| | Box No. VI | Certain documents cited |
| \boxtimes | Box No. VII | Certain defects in the international application |
| | Box No. VIII | Certain observations on the international application |

FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office

D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Authorized Officer

Escolar Blasco, P

Telephone No. +49 89 2399-7331



| _ | | |
|----|---------|---|
| _ | Box N | lo. I Basis of the opinion |
| 1. | With r | egard to the language , this opinion has been established on the basis of the international application in nguage in which it was filed, unless otherwise indicated under this item. |
| | lè | his opinion has been established on the basis of a translation from the original language into the following nguage , which is the language of a translation furnished for the purposes of international search under Rules 12.3 and 23.1(b)). |
| 2. | With r | egard to any nucleotide and/or amino acid sequence disclosed in the international application and sary to the claimed invention, this opinion has been established on the basis of: |
| | a. type | e of material: |
| | | a sequence listing |
| | | table(s) related to the sequence listing |
| | b. forn | nat of material: |
| | | in written format |
| | | in computer readable form |
| | c. time | of filing/furnishing: |
| | | contained in the international application as filed. |
| | | filed together with the international application in computer readable form. |
| | | furnished subsequently to this Authority for the purposes of search. |
| 3. | CC | addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto is been filed or furnished, the required statements that the information in the subsequent or additional pies is identical to that in the application as filed or does not go beyond the application as filed, as propriate, were furnished. |
| 4. | Additio | nal comments: |

| | Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | |
|-------------|---|------------------|--|--|--|--|--|
| The | The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of: | | | | | | |
| | the entire international applicat | ion, | | | | | |
| \boxtimes | claims Nos. 1-21, in respect of | IA | | | | | |
| bec | ause: | | | | | | |
| \boxtimes | the said international application, or the said claims Nos. 1-21 relate to the following subject matter which does not require an international preliminary examination (specify): | | | | | | |
| | see separate sheet | | | | | | |
| | the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): | | | | | | |
| | the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. | | | | | | |
| | no international search report h | nas b | een established for the whole application or for said claims Nos. | | | | |
| | the nucleotide and/or amino ac C of the Administrative Instruct | id sec ions i | quence listing does not comply with the standard provided for in Annex in that: | | | | |
| | the written form | | has not been furnished | | | | |
| | | | does not comply with the standard | | | | |
| | the computer readable form | | has not been furnished | | | | |
| | | | does not comply with the standard | | | | |
| | the tables related to the nucleonot comply with the technical re | otide a equir | and/or amino acid sequence listing, if in computer readable form only, do ements provided for in Annex C-bis of the Administrative Instructions. | | | | |
| | See separate sheet for further details | | | | | | |

International application No. PCT/US2005/010146

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

8,11-21

No: Claims

1-7,9,10

Inventive step (IS)

Yes: Claims

No: Claims

1-21

Industrial applicability (IA)

Yes: Claims

see separate sheet

No: Claims

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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| | | | ALITH LOCATIV |
| -IN | TERNATIONAL | SEARCHING | AUTHORITY |

BOSTON SCIENTIFIC SCIMED, INC.

To: WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International filing date (day/month/year) Priority date (day/month/year) International application No. 29.03.2005 30.03.2004 PCT/US2005/010146 International Patent Classification (IPC) or both national classification and IPC A61K35/28, A61P9/10 Applicant

| 1. | This opinion | contains indications | relating to | the following | items: |
|----|--------------|----------------------|-------------|---------------|--------|
|----|--------------|----------------------|-------------|---------------|--------|

| Box No. I | Basis of the opinion |
|---|--|
| ☐ Box No. II | Priority |
| ☑ Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ Box No. IV | Lack of unity of invention |
| Box No. V ■ Box No. V ■ Box No. V ■ Dox No. V Dox No. | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ Box No. VI | Certain documents cited |
| Box No. VII | Certain defects in the international application |
| ☐ Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

<u>)</u>

European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 Authorized Officer

Escolar Blasco, P

Telephone No. +49 89 2399-7331



| _ | | | | |
|----|---|-------|--|--|
| | Во | x No | o. I Basis of the opinion | |
| 1. | With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item. | | | |
| | | icai | is opinion has been established on the basis of a translation from the original language into the following guage , which is the language of a translation furnished for the purposes of international search ider Rules 12.3 and 23.1(b)). | |
| 2. | Wit | th re | gard to any nucleotide and/or amino acid sequence disclosed in the international application and ary to the claimed invention, this opinion has been established on the basis of: | |
| | a. t | ype | of material: | |
| | | | a sequence listing | |
| | İ | | table(s) related to the sequence listing | |
| | b. f | orma | at of material: | |
| | ! | | in written format | |
| | I | | in computer readable form | |
| | c. ti | me d | of filing/furnishing: | |
| | [|] | contained in the international application as filed. | |
| | [|] : | filed together with the international application in computer readable form. | |
| | E |] 1 | furnished subsequently to this Authority for the purposes of search. | |
| 3. | | cop | addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto been filed or furnished, the required statements that the information in the subsequent or additional ies is identical to that in the application as filed or does not go beyond the application as filed, as ropriate, were furnished. | |
| 4. | Add | ition | al comments: | |

| Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | |
|---|---|--|-----------------------------------|--|--|--|
| The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of: | | | | | | |
| | the entire international application, | | | | | |
| \boxtimes | claims Nos. 1-21, in respect of IA | | | | | |
| because: | | | | | | |
| \boxtimes | the said international application, or the said claims Nos. 1-21 relate to the following subject matter which does not require an international preliminary examination (specify): | | | | | |
| | see separate sheet | | | | | |
| | the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): | | | | | |
| | the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. | | | | | |
| | no international search report has been established for the whole application or for said claims Nos. | | | | | |
| | the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: | | | | | |
| | the written form | | has not been furnished | | | |
| | | | does not comply with the standard | | | |
| | the computer readable form | | has not been furnished | | | |
| | · | | does not comply with the standard | | | |
| | the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions. | | | | | |
| | ☐ See separate sheet for further details | | | | | |